1 Claims

2

3

- 4 1. A pharmaceutical formulation comprising an
- 5 active agent and at least one excipient, wherein at
- 6 the least one excipient comprises a β -limit dextrin.

7

- 8 2. A pharmaceutical formulation as claimed in
- 9 Claim 1 in which the β -limit dextrin is a carrier
- 10 for the active agent.

11

- 12 3. A pharmaceutical formulation as claimed in
- 13 Claims 1 or 2 in which the active agent is a
- 14 pharmaceutically active agent.

15

- 16 4. A pharmaceutical formulation as claimed in
- 17 Claims 1, 2 or 3 which is a bioadhesive
- 18 pharmaceutical formulation.

19

- 20 5. A bioadhesive pharmaceutical formulation as
- 21 claimed in Claim 4 which is a buccal-melt type
- 22 product.

23

- 24 6. A bioadhesive pharmaceutical formulation as
- 25 claimed in Claim 5 which is a wafer.

26

- 27 7. A bioadhesive pharmaceutical formulation as
- 28 claimed in Claim 4 which is a powder for use in
- 29 aerosol delivery formulations.

- 31 8. A bioadhesive pharmaceutical formulation as
- 32 claimed in Claim 4 which is a thin film.

1

2 9. A bioadhesive pharmaceutical formulation as

3 claimed in any of Claims 4 to 8 further including at

4 least one carbohydrate.

5

6 10. A bioadhesive pharmaceutical formulation as

7 claimed in Claim 9 in which the at least one

8 carbohydrate is a polysaccharide.

9

10 11. A bioadhesive pharmaceutical formulation as

11 claimed in Claim 9 in which the at least one

12 carbohydrate is selected from the group comprising:

13 alginate; pectin; and derivatives of alginate and

14 pectin.

15

16 12. A bioadhesive pharmaceutical formulation as

17 claimed in Claim 11 in which the alginate comprises

18 between 1 and 50% of the formulation (w/w).

19

20 13. A bioadhesive pharmaceutical formulation as

21 claimed in Claim 12 in which the alginate comprises

22 between 10 and 30% of the formulation (w/w).

23

24 14. Use of β -limit dextrin as a mucoadhesive

25 carrier.

26

27 15. Use of β -limit dextrin as a mucoadhesive

28 carrier in a pharmaceutical formulation.

29

30 16. Use of β -limit dextrin as a mucoadhesive

31 carrier in a thin-film breath freshener.

1 17. A pharmaceutical formulation as claimed in

2 Claim 1 or 2 which is a buccal melt product.

3

- 4 18. A pharmaceutical formulation as claimed in any
- 5 preceding Claim in a form selected from the group
- 6 comprising: particulate; capsule; tablet; freeze
- 7 dried matrix; wafer; and liquid.

8

- 9 19. A liquid pharmaceutical formulation comprising
- 10 an active agent, and a dispersant for the active
- 11 agent, wherein the dispersant comprises a β -limit
- 12 dextrin.

13

- 14 20. Use of β -limit dextrin as a dispersant in
- 15 liquid pharmaceutical formulations.

16

- 17 21. Use of β -limit dextrin as an excipient in a
- 18 pharmaceutical formulation.

19

- 20 22. A nutritional product comprising β -limit
- 21 dextrin.

22

- 23 23. A nutritional product as claimed in Claim 22 in
- 24 which the β -limit dextrin is a main energy source in
- 25 the product.

26

- 27 24. A nutritional product as claimed in Claim 22 or
- 28 23 which is an energy drink.

- 30. 25. A nutritional product as claimed in Claim 22 or
- 31 23 which is a confectionery product.

WO 2004/014156 40

PCT/EP2003/008358

1

26. Use of $\beta\text{-limit}$ dextrin as an energy source in a 2

3 nutritional product.

4

27. Use of $\beta\text{-limit}$ dextrin as an energy source in 5

6 an energy drink.

7

28. Use of β -limit dextrin as a 8 carrier of

nutrients in an energy drink. 9

10

11 A formulation, product, or use as claimed in

any preceding Claim in which the $\beta\text{-limit}$ dextrin is 12

13 obtainable by hydrolysing starch.

14

30. A formulation, product, or use as claimed in 15

Claim 29 in which the β -limit dextrin is obtainable 16

by hydrolysing starch with β -amylase. 17

18

31. A formulation, product, or use as claimed in 19

Claim 29 or 30 in which the starch is a waxy starch. 20

WO 2004/014156

PCT/EP2003/008358

AMENDED CLAIMS

1 [received by the International Bureau on 12 March 2004 (12.03.04); original claims 1 to 31 replaced by amended claims 1 to 25;] 2 3 formulation pharmaceutical bioadhesive 4 agent and а mucoadhesive active 5 comprising an wherein active agent, for the 6 carrier mucoadhesive carrier comprises a β -limit dextrin. 7 8 A bioadhesive pharmaceutical formulation 9 claimed in Claim 1 in which the β -limit dextrin is 10 obtainable by hydrolysing starch with β -amylase. 11 12 A bioadhesive pharmaceutical formulation 13 claimed in Claims 1 or 2 in which the active agent is a pharmaceutically active agent. 15 16 A bioadhesive pharmaceutical formulation as 17 claimed in any preceding claim which is a buccal-18 19 melt type product. 20 A bioadhesive pharmaceutical formulation as 21 claimed in Claim 4 which is a wafer. 22 23 A bioadhesive pharmaceutical formulation as 24 claimed in any of Claims 1 to 3 which is a powder 25 for use in aerosol delivery formulations. 26 27 A bioadhesive pharmaceutical formulation as 28 claimed in any of Claims 1 to 3 which is a thin 29 film. 30 31

1 8. A bioadhesive pharmaceutical formulation as

- 2 claimed in any preceding claims further including at
- 3 least one carbohydrate.

4

- 5 9. A bioadhesive pharmaceutical formulation as
- 6 claimed in Claim 8 in which the at least one
- 7 carbohydrate is a polysaccharide.

8

- 9 10. A bioadhesive pharmaceutical formulation as
- 10 claimed in Claim 8 in which the at least one
- 11 carbohydrate is selected from the group comprising:
- 12 alginate; pectin; and derivatives of alginate and
- 13 pectin.

14

- 15 11. A bioadhesive pharmaceutical formulation as
- 16 claimed in Claim 10 in which the alginate comprises
- 17 between 1 and 50% of the formulation (w/w).

18

- 19 12. A bioadhesive pharmaceutical formulation as
- 20 claimed in Claim 11 in which the alginate comprises
- 21 between 10 and 30% of the formulation (w/w).

22

- 23 13. Use of β -limit dextrin as a mucoadhesive
- 24 carrier.

25

- 26 14. Use of β -limit dextrin as a mucoadhesive
- 27 carrier in a pharmaceutical formulation.

28

- 29 15. Use of β -limit dextrin as a mucoadhesive
- 30 carrier in a thin-film breath freshener.

1 16. A bioadhesive pharmaceutical formulation as

- 2 claimed in any of Claims 1 to 12 in a form selected
- 3 from the group comprising: particulate; capsule;
- 4 tablet; freeze dried matrix; wafer; liquid; and thin
- 5 film.

6

- 7 17. A nutritional product comprising eta-limit
- 8 dextrin in which the β -limit dextrin is a main
- 9 energy source in the product.

10

- 11 18. A nutritional product as claimed in Claim 17
- 12 which is an energy drink.

13

- 14 19. A nutritional product as claimed in Claim 17 or
- 15 18 which is a confectionery product.

16

- 17 20. Use of β -limit dextrin as an energy source in a
- 18 nutritional product.

19

- 20 21. Use of β -limit dextrin as a slow release energy
- 21 source in a nutritional product.

22

- 23 22. Use as claimed in Claim 20 or 21 in which the
- 24 nutritional product is an energy drink.

25

- 26 23. A formulation, or use, as claimed in any
- 27 preceding Claim in which the β -limit dextrin is
- 28 obtainable by hydrolysing starch.

1 24. A formulation, or use, as claimed in Claim 23

- 2 in which the β -limit dextrin is obtainable by
- 3 hydrolysing starch with β -amylase.

- 5 25. A formulation, or use as claimed in Claim 23 or
- 6 24 in which the starch is a waxy starch.